REMARKS

Election/Restrictions

Claims 40-55 have been withdrawn from consideration as being drawn to a non-elected species of the invention. The Applicant has cancelled claims 40-55 without prejudice for possible submission in a continuing application.

Claim Rejections - 35 USC §112

Claims 29, 32 and 39 have been rejected as being indefinite under 35 USC §112, second paragraph. The Applicant has cancelled claims 29 and 32 without prejudice for submission in a continuing application. Claim 39 has been amended to address the antecedent basis informality. The Applicant is believed to have addressed each of the rejections set under 35 USC §112, second paragraph. Accordingly, withdrawal of the claim rejections under 35 USC §112, second paragraph is respectfully requested.

Claim Rejections – 35 USC §102 and 103

Claims 1, 2, 5, 6, 8, 9, 21, 26, 27 and 29 were rejected under 35 U.S.C. §102(a) or §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0093153 to Banick et al. (hereafter "the Banick reference"). Claims 1, 2, 5-9, 17, 20, 21 and 29 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,306,309 to Wagner et al. (hereafter "the Wagner reference"). Claims 1-4, 17, 30, 36, 37 and 39 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0004660 to Henniges et al. (hereafter "the Henniges reference").

Additionally, claims 22-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Banick reference in view of U.S. Patent No. 4,523,679 to Paikoff et al. (hereafter "the Paikoff reference"), and claim 28 was rejected under 35 U.S.C. §103(a) as being unpatentable over the Banick reference as a matter of obvious design choice. Claims 10-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Wagner reference in view of U.S. Patent No. 5,346,929 to Guttag (hereafter "the Guttag reference"). Claims 18, 19 and 38 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Henniges reference in view of U.S.

Patent No. 5,901,622 to Sweeny (hereafter "the Sweeny reference"). Claims 31 and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Henniges reference in view of U.S. Patent No. 6,322,562 to Wolter (hereafter "the Wolter reference"). Finally, claims 30 and 33-35 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,610,093 to Pisharodi (hereafter "the Pisharodi reference") in view of the Wagner reference.

It is well established that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Independent Claim 1 and Dependent Claims 2-28

Independent claim 1 and dependent claim 2 have been cancelled without prejudice for possible submission in a continuing application. Dependent claim 3 has been rewritten in independent form, and dependent claims 5, 7, 8, 17, 22, 24 and 26 (originally depending from independent claim 1) have been amended to depend from rewritten independent claim 3, dependent claim 20 (originally depending from independent claim 1) has been amended to depend from dependent claim 17, and dependent claim 23 (originally depending from independent claim 1) has been amended to depend from dependent claim 24.

Rewritten Independent Claim 3 and Dependent Claims 4-9, 17, 20 and 22-26

Rewritten independent claim 3 is directed to a surgical kit for use in spinal surgery and recites, in pertinent part, a spinal implant including an elongate member and a number of bone anchors adapted to secure the elongate member to first and second vertebrae, instrumentation adapted for use in association with the spinal surgery, and packaging adapted to integrally contain and maintain the spinal implant and the instrumentation in a common container in a sterilized condition prior to the spinal surgery.

Original claim 3 was solely rejected as being anticipated by the Henniges reference, and was not substantively rejected based on the teachings of any other patent reference. The grounds for the rejection of claim 3 are set forth on page 4 of the Office Action; namely, "Fig. 1 shows a

surgical plate 10 and a number of bone screws 12 to secure the plate. Fig. 11A shows a driver instrument 24 . . . . Henniges et al. discloses the equipment is packaged, paragraph 60. It is inherent the surgical kit maintained in sterile conditions, since doctors will not risk using unsterile equipment on a patient, which could cause infections."

Albeit that the Henniges reference may disclose a plate 10, fasteners 12 for attaching the plate 10 to bone, and a driver 24 for driving the fasteners 12 into engagement with bone, these components are clearly not enclosed in packaging which integrally contains and maintains each of the plate 10, the fasteners 12 and the driver 24 in a common container in a sterilized condition prior to the spinal surgery, as substantially recited in rewritten independent claim 3. To the contrary, the Henniges reference discloses that the plates 10 are contained in plate packaging (paragraphs 59 and 60), the fasteners 12 are contained in a separate container 76 (paragraph 79), and the driver 24 and other tools are contained within yet another separate instrument container (Figure 31). Accordingly, although the Henniges reference appears to disclose plates 10, fasteners 12 and a driver 24, there is no indication or suggestion that each of these components are integrally contained and maintained in a common container in a sterilized condition prior to surgery, as substantially recited in rewritten independent claim 3. Instead of providing a self-contained kit which packages spinal components (including an elongate support member and bone anchors) and the instrumentation necessary to perform a designated spinal surgical procedure within a common, sterilized container, the Henniges reference specifically teaches that the components and instruments are packaged separately from one another, which is directly contrary to the inventive concept recited in independent claim 3.

Indeed, the Henniges reference discloses specific features for ensuring that the appropriate plate 10 and fasteners 12 are selected from product inventory for a particular surgical procedure. Specifically, the Henniges reference discloses that various plates 10 are color coded for identification purposes to ensure selection of the appropriate plate for the surgical procedure. ("The plates 10 can come in several different sizes and shapes depending on the specific application. By manufacturing the plates 10 with a unique color associated with each unique shape and size, confusion will be minimized and time will be saved.") (paragraph 59). Additionally, the Henniges reference discloses that "the package containing bioabsorbable plates

10 are marked with an identification mark, not shown. The mark allows the package with the plates 10 to be identified more precisely . . . in a manner that will allow the nurse or doctor to easily read and recognize the identification mark and the corresponding mark on the package containing the plate 10." Likewise, "color coding of the fasteners 12 will allow easy and quick identification of different fasteners 12" to ensure selection of the appropriate fasteners for the surgical procedure. (Paragraph 67).

Accordingly, the Henniges reference fails to disclose or suggest the concept of providing a self-contained kit which integrally contains and maintains spinal components (including an elongate support member and bone anchors) and instrumentation necessary to perform a designated spinal surgical procedure within a common container in a sterilized container, as substantially recited in rewritten independent claim 3. Indeed, the Henniges reference seems to specifically teach away from this inventive concept, instead teaching that the plates 10 are contained within separate packages that are colored coded and individually marked to facilitate selection of an appropriate plate from product inventory, and that the fasteners 12 are likewise contained within separate packages that are colored coded and individually marked to facilitate selection of appropriate fasteners from product inventory.

The drawbacks and disadvantages associated with selecting surgical components and instruments from product inventory are specifically discussed in the background section of the subject application at page 1, line 18 to page 2, line 6. Specifically, the background section of the subject application sets forth the following:

> Many different types and sizes of implants, devices and instruments are available for treating various diseases, pathologies, injuries or malformations affecting the spine. In the past, the components required for a spinal surgical procedure have been supplied individually to surgical facilities, such as hospitals, trauma or ambulatory centers, medical or research laboratories, and surgical training facilities. Relatively high levels of inventory have been procured and maintained to accommodate the varying requirements associated with a spinal surgical procedure (e.g., anatomical requirements that dictate the selection of a particular size and configuration of implant, device and/or surgical instrument).
>
> As should be appreciated, high inventory levels are expensive to procure and maintain, and are subject to loss, damage and possible theft. Moreover, the cost of even the most basic of surgical instrumentation can be quite high. Additionally, the availability of implants, devices and surgical instrumentation

> may be scarce, particularly with regard to remote or under-represented surgical facilities. Cleaning, sterilizing and maintaining surgical components can be both time consuming and expensive, particularly with regard to surgical instrumentation that is designed for repeated use. Additionally, cleaning and sterilization procedures may result in significant wait or down time in cases involving back-to-back scheduling of multiple surgical procedures.

The drawbacks and disadvantages discussed in the background section of the subject application are inherent in the individual packaging technique disclosed in the Henniges reference. However, the inventive concept recited in rewritten independent claim 3 addresses the drawbacks and disadvantages of individually packaging components and instrumentation from product inventory by providing a self-contained kit which integrally contains and maintains the components and instrumentation necessary to perform a designated spinal surgical procedure within a common container in a sterilized condition. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 3 as being anticipated by the Henniges reference and allowance of the same.

Additionally, although original claim 3 was not substantively rejected based on the teachings of any other patent reference, the Applicant also notes that none of the other patent references of record teach or suggest the concept of providing a self-contained kit which integrally contains and maintains spinal components, including an elongate support member, bone anchors, and instrumentation within a common container in a sterilized condition.

Claims 4-9, 17, 20 and 22-26 depend from rewritten independent claim 3, and are submitted to be patentable for at least the reasons set forth above with regard to the patentability of independent claim 3. Additionally, further reasons support the patentability of these dependent claims. For example, claim 5 further recites that the spinal implant included within the surgical kit and integrally contained and maintained within the common container further comprises an interbody implant adapted for disposition within an intervertebral space between first and second vertebrae, and claim 6 recites that the surgical kit further includes a bone growth promoting substance to facilitate interbody fusion. The Henniges reference fails to disclose or suggest any type of interbody spinal implant, or the inclusion of a bone growth promoting substance to facilitate interbody fusion.

Additionally, claim 24 recites that the packaging comprises an inner container and outer container, with the inner container adapted to contain and maintain the spinal implant and the instrumentation in the sterilized condition, and the outer container adapted to contain and maintain the inner container in a sterilized condition prior to the spinal surgery, and claim 23 further recites that the inner container and the outer container are each formed of a material capable of providing direct visualization of the spinal implant and the instrumentation contained therein. The Henniges reference fails to disclose or suggest packing including both inner and outer containers which serve to maintain a sterilized condition. Furthermore, claim 25 further recites that the outer container includes a first removable seal to provide selective access to the inner container, and the inner container includes a second removable seal to provide selective access to the spinal implant and the instrumentation contained therein. Once again, these features are neither disclosed nor suggested by the Henniges reference.

Rewritten Independent Claim 10 and Dependent Claims 11-16, 21 and 56-59

Rewritten independent claim 10 is directed to a surgical kit for use in spinal surgery and recites, in pertinent part, a spinal implant, instrumentation adapted for use in association with the spinal surgery, and packaging adapted to contain and maintain the spinal implant and the instrumentation in a sterilized condition prior to the spinal surgery, and "wherein at least a portion of said instrumentation is subject to degradation upon exposure to a sterilization procedure."

Original claim 10 was solely rejected as being unpatentable over the Wagner reference in view of the Guttag reference, and was not substantively rejected based on the teachings of any other patent reference of record, whether considered alone or in combination. The grounds for the rejection of claim 10 are set forth on page 6 of the Office Action. In summary, the Wagner reference is indicated as failing to disclose instrumentation that is subject to degradation upon exposure to sterilization. Nevertheless, the Guttag reference is asserted to teach this feature of the claimed invention. The Applicant respectfully disagrees with this assertion for at least the following reasons.

First, although the Guttag reference discusses biodegradation of a polymer material, there is no teaching or suggestion whatsoever regarding degradation resulting from a sterilization procedure used to sterilize surgical instrumentation. Furthermore, there is no indication or suggestion in the Guttag reference regarding the fabrication of surgical instruments that are used in association with a surgical kit which includes a spinal implant and packaging for containing and maintaining the instrumentation and the spinal implant in a sterilized condition. The inventive concept recited in independent claim 10 regarding degradation of at least a portion of the instrumentation upon exposure to a sterilization procedure is meant to limit the number of surgical procedures with which the instrumentation is used. In some cases, this would constitute a single sterilization procedure to deter or prevent use of the instrumentation after the initial use. However, the purpose of the biodegradable polymer disclosed in the Guttag reference is to provide relatively slow biodegradation resulting from exposure to natural environmental factors. As indicated above, the Guttag reference fails to disclose or suggest degradation resulting from a sterilization procedure of surgical instruments, which is the focus of the inventive concept recited in independent claim 10.

Since each of the features recited in independent claim 10 are neither disclosed nor suggested in the Wagner reference, the Guttag reference, or any of the references of record, the Applicant submits that a prima facia case of obviousness has not been established. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 10 and allowance of the same. Additionally, dependent claims 11-16 recite additional features associated with the recited degradation and sterilization procedure, which likewise are not specifically disclosed or suggested by the Wagner reference, the Guttag reference, or any of the references of record. New claims 56-59 depend from rewritten independent claim 10 and are submitted to be patentable for at least the reasons set forth above with regard to the patentability of independent claim 10. The Applicant specifically notes that dependent claim 56 recites that "said at least a portion of said instrumentation subject to degradation upon exposure to said sterilization procedure is formed of a metallic material." This Guttag reference fails to disclose or suggest that the biodegradable material comprises a metallic material. Instead, the biodegradable material is disclosed as comprising a plastic or polymeric material.

Rewritten Independent Claim 18 and Dependent Claims 19 and 60-69

Rewritten independent claim 18 is directed to a surgical kit for use in spinal surgery and recites, in pertinent part, a spinal implant, instrumentation adapted for use in association with the spinal surgery, and packaging adapted to contain and maintain the spinal implant and the instrumentation in a sterilized condition prior to the spinal surgery, and "wherein said instrumentation comprises a first portion and a second portion, said first portion of said instrumentation comprises a shaft, said second portion of said instrumentation comprising a handle, said shaft including opposite first and second end portions, said first and second end portions being reversible relative to said handle, said first end portion adapted to perform a first function associated with the spinal surgery, said second end portion adapted to perform a second function associated with the spinal surgery."

Original claim 18 was solely rejected as being unpatentable over the Henniges reference in view of the Sweeny reference, and was not substantively rejected based on the teachings of any other patent reference of record, whether considered alone or in combination. As an initial matter, the Applicant submits that the Sweeny reference is not "within the field of the inventor's endeavor." In re Deminski, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986), which is a well-established standard for establishing a prima facia case of obviousness. Likewise, the Sweeny reference is not within the field of endeavor of the Henniges reference, which is the combination of references relied in the rejection of independent claim 18.

Specifically, the Sweeny reference discloses a screw driver for use as a conventional hand tool, there being no teaching or suggestion whatsoever that the screw driver may be used in surgical applications, much less included within a surgical kit in combination with a spinal implant. Nor is there any indication or suggestion that the screw driver be combined with a spinal implant in packaging to contain and maintain the screw driver and the spinal implant in a sterilized condition prior to a spinal surgery. Indeed, the screw driver is provided with a storage compartment 11 in the handle 1 which is accessed via removal of a plastic cap 14. Such features would not be included in a surgical instrument due to sterilization issues and the risks associated with the cap 14 being inadvertently removed during a surgical procedure which could result in dislodgement of the contents from the storage compartment and into the body. Additionally, the

screw driver is disclosed as having a magnetic pickup, which would not be applicable for use in association with surgical components that are typically formed of titanium or stainless steel.

For at least these reasons, the Applicant submits that there would have been no motivation to combine the teachings of the Sweeney reference with the Henniges reference to arrive at the invention recited in independent claim 18. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 18 and allowance of the same. Claim 19 and new claims 60-69 depend from rewritten independent claim 18, and are submitted to be patentable for at least the reasons set forth above with regard to the patentability of independent claim 18.

Rewritten Independent Claim 27 and Dependent Claims 28 and 70-72

Rewritten independent claim 27 is directed to a surgical kit for use in spinal surgery and recites, in pertinent part, a spinal implant, instrumentation adapted for use in association with the spinal surgery, a template including a number of images corresponding to one or more select sizes of said spinal implant, with one of the template images corresponding to a size of the spinal implant included with the surgical kit, and packaging adapted to contain and maintain the spinal implant and the instrumentation in a sterilized condition prior to the spinal surgery, and wherein "said template is provided external to said packaging to provide access to said template without compromising said sterilized condition of said spinal implant and said instrumentation".

Original claim 27 was solely rejected as being anticipated by the Banick reference, and was not substantively rejected based on the teachings of any other patent reference. The grounds for the rejection of claim 27 are set forth on pages 3 and 4 of the Office Action; namely that "Banick also discloses the template or instructions can be provided external to the packaging to maintain sterile conditions for the implant, paragraph 37." The Applicant respectfully disagrees with this assertion.

Even assuming arguendo that the other elements and features of rewritten independent claim 27 are disclosed in the Banick reference, the element 64 is referred to solely as "instructions of use". One of ordinary skill in the art would understand that "instructions of use" comprise a writing or document that sets forth a method or technique for using a particular

component, and does not refer to "a template including a number of images" that correspond to select sizes of a spinal implant, with "one of the template images corresponding to a size of the spinal implant included with the surgical kit". Indeed, the Banick reference fails to disclose or suggest that the instructions of use 64 include images that correspond to select sizes of a spinal implant, with one of the template images specifically corresponding to the size of the spinal implant included with the surgical kit. Moreover, the Banick reference specifically discloses that the components of the kit 60, including the instructions of use 64, "are contained within a sterile package 66" (paragraph 37). The Banick reference also discloses that other embodiments of kits only include an implant 20, without an insertion tool 54 or instructions of use 64. However, the Banick reference does not disclose kit embodiments which include an implant 20, an insertion tool 54 and instructions of use 64, with only the instructions 64 being provided external to the packaging. Accordingly, the Banick reference fails to disclose or suggest the elements and features recited in rewritten independent claim 27.

One of the advantages provided by the inventive concept recited in rewritten independent claim 27 is set forth in the subject application on page 12, lines 15-23. Specifically, the subject application discloses that "the template 50 can be accessed by a surgeon or other medical personnel without having to open the packing 14. Accordingly, the sterility of the inner packaging container 30 and/or the surgical equipment 12 contained therein is not compromised in the event that the particular size and/or configuration of the spinal implant 20 and/or bone anchors 22 included with the surgical kit 10 fail to satisfy the particular requirements of the designated spinal surgical procedure." This advantage is not realized by the Banick reference since mere instructions of use 64 can not be used to verify that the particular size and/or configuration of the spinal implant 20 contained within the sterile packaging 66 is suitable for the particular surgical procedure. Additionally, since the instructions of use 64 are specifically disclosed as being contained within the sterile packaging 66, accessing the instructions of use would necessarily require opening the packaging 66, which would in turn compromise the sterility of the components contained within the packaging 66.

For at least the reasons set forth above, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 27 as being anticipated by the Banick reference and

allowance of the same. Additionally, although claim 27 was not substantively rejected based on the teachings of any other patent reference, the Applicant also notes that none of the other patent references of record teach or suggest the elements and features recited in rewritten independent claim 27.

Claims 28 and 70-72 depend from rewritten independent claim 27, and are submitted to be patentable for at least the reasons set forth above with regard to the patentability of independent claim 27. Additionally, further reasons support the patentability of claim 28 which recites that the template includes a magnification factor associated with the template images. Indeed, the Banick reference fails to disclose or suggest that the instructions of use 64 include such a feature.

Independent Claim 30 and Dependent Claims 31 and 33-39

As an initial matter, dependent claim 32 has been cancelled without prejudice for possible submission in a continuing application.

Independent claim 30 has been amended to recite, in pertinent part, a surgical kit comprising a surgical equipment set including a spinal plate, a number of bone screws adapted to secure the spinal plate to first and second vertebrae, and a driver instrument adapted to drive the bone screws into engagement with vertebral bone, and "packaging adapted to integrally contain and maintain said surgical equipment set in a common container in a sterilized condition prior to the spinal surgery."

Independent claim 30 was rejected as being anticipated by the Henniges reference, and as being unpatentable over the Pisharodi reference in view of the Wagner reference. As indicated above with regard to rewritten independent claim 3, albeit that the Henniges reference may disclose a plate 10, fasteners 12 for attaching the plate 10 to bone, and a driver 24 for driving the fasteners 12 into engagement with bone, these components are not enclosed in packaging which integrally contains and maintains each of the plate 10, the fasteners 12 and the driver 24 in a common container in a sterilized condition prior to the spinal surgery, as substantially recited in rewritten independent claim 30. To the contrary, the Henniges reference discloses that the plates 10 are contained in plate packaging (paragraphs 59 and 60), the fasteners 12 are contained in a

separate container 76 (paragraph 79), and the driver 24 and other tools are contained within yet another separate instrument container (Figure 31). Accordingly, for reasons similar to those discussed above with regard to independent claim 3, the Applicant submits that independent claim 30, as amended, is not anticipated by the Henniges reference, and withdrawal of the rejection of independent claim 30 based on this reference is respectfully requested.

Furthermore, neither the Pisharodi reference nor the Wagner reference discloses each of the elements and features recited in independent claim 30. Indeed, neither of these references discloses a surgical kit comprising a spinal plate, a number of bone screws, a driver instrument, and "packaging adapted to integrally contain and maintain said surgical equipment set in a common container in a sterilized condition prior to the spinal surgery." On page 7 of the Office Action, it is asserted that it is "inherent that . . . the surgical equipment would be packaged and maintained sterile for the surgeon to use in a patient." While it may be true that surgical equipment is almost always sterilized prior to use, it is not inherent that such instrumentation is included within a surgical kit including a spinal plate, a number of bone screws, and a driver instrument, nor is it inherent that such components be provided in "packaging adapted to integrally contain and maintain said surgical equipment set in a common container in a sterilized condition prior to the spinal surgery." The Applicant's reasons supporting this position are similar to those discussed above with regard to independent claim 3. Accordingly, the Applicant submits that independent claim 30, as amended, is not unpatentable over the Pisharodi reference in view of the Wagner reference, and withdrawal of the rejection of independent claim 30 on this ground is respectfully requested.

For at least the reasons set forth above, the Applicant respectfully requests withdrawal of the rejections of independent claim 30 and allowance of the same. Additionally, claims 31 and 33-39 depend from independent claim 30, and are submitted to be patentable for at least the reasons set forth above with regard to the patentability of independent claim 30. Additionally, further reasons support the patentability of claims 31 and 33-39. For example, claim 33 is patentable for reasons similar to those discussed above with regard to claim 5, claim 35 is patentable for reasons similar to those discussed above with regard to independent claim 10, claim 38 is patentable for reasons similar to those discussed above with regard to independent

claim 18, and claim 39 is patentable for reasons similar to those discussed above with regard to independent claim 27.

Independent Claim 40 and Dependent Claims 41-55

Claims 40-55 have been cancelled without prejudice for possible submission in a continuing application.

New Dependent Claims 56-72

New dependent claims 56-72 have been added and are submitted to be patentable for at least the reasons set forth above with regard to patentability of their respective independent base claims.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 3-28, 30, 31, 33-39 and 56-72.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: _____

Brad A. Schepers
Reg. No. 45,431
Krieg DeVault LLP
One Indiana Square, Suite 2800
Indianapolis, Indiana 46204-2079
(317) 238-6334 voice
(317) 238-6371 facsimile